REMARKS

In the non-final Office Action mailed on August 21, 2009, claims 1-4, 6, 8-21, 23-24, and 43-48 were rejected. Claims 1-4, 6, 8-21, 23-24, 32-39 and 43-48 are pending.

I. Rejection under 35 USC § 112, first paragraph, enablement

Claims 1-4, 6, 8-21, 23-24, and 43-48 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not being enabling for the claimed scope.

Applicants respectfully traverse the rejection and its supporting remarks. Applicants acknowledge that the field of adjuvants is quite unpredictable. The immune system is quite complicated which allows it to adapt to a wide range of different pathogens including bacteria, viruses, fungi and parasitic organisms such as malaria. Further, the immune system must be able to adapt to pathogens with different modes of infection, such as infections in the blood, infections in the gut, etc. Thus, it is unpredictable whether a given adjuvant will be able to induce a response that is protective against a given organism such as *Neisseria meningitidis* given that adjuvants have different modes of action. Furthermore, it is even more unpredictable when combining adjuvants again because of the different modes of action.

However, the claims are fairly supported by working example in the specification. The specification demonstrates the efficacy of SEQ ID NO: 1 (an oligonucleotide comprising at least one CG motif) with CFA (an emulsion comprising submicron oil droplets and an emulsifying agent). As adjuvants, CFA, MF59 and IFA all share in common the fact that they are oil-in-water adjuvants. As oil-in-water adjuvants, they will therefore share a common mechanism of enhancing the immune response. Thus, while they may differ in the degree of immune response, they will still produce a similar type of immune response. As shown in table 2, all three of these adjuvants produced a fairly similar level of immune response. Thus, while there may be unpredictability as to whether an oil in water adjuvant will work to produce a protective immune response to a given bacteria and unpredictability as to whether an oil in water adjuvant will produce a superior protective immune response to a given bacteria when combined with another class of adjuvant,

given that the specification shows that three oil-in-water adjuvants produce generally similar levels of protection and one exemplary oil-in-water adjuvant shows a superior level of protection when combined with an oligonucleotide comprising at least one CG motif, one of skill in the art would not need to engage in undue experimentation when testing other oil-in-water adjuvants.

Similarly, oligonucleotides comprising at least one CG motif are a known class of adjuvants. While not completely understood, Krieg (BioDrugs 1998, 5:341-346) sets out the mode of action of such oligonucleotides. Since they share a common mode of activity, a single example of an oligonucleotide comprising at least one CG motif working in conjunction with an oil-in-water adjuvant to produce a superior immune response to a given bacteria is sufficient. One of skill in the art would not require undue experimentation to test other oligonucleotides comprising at least one CG motif. This is especially true in light of the state of the art as of the priority date. The Examiner suggests that the fact that Krieg teaches an oligo length of 8 to 30 and at least a single CpG not preceded by a C or followed by a G is relevant as such details are not found in the claims. However, the relevant question for enablement is not what details are in the claims, but rather what does the specification ***and the state of the art as of the priority date*** teach. One of skill in the art seeking to practice the claimed invention as of the priority date would have Krieg available as a manual to guide the experimental design. The same is true for most of the other articles cited by the Examiner, i.e., they actually were available as of the priority date and therefore support the assertion that undue experimentation was not required due to such articles being available to assist one of skill in the art in designing a suitable oligonucleotides comprising at least one CG motif. Finally, the Examiner notes that the lack of methylation of the CpG motif is important for the immunostimulatory effect, but this detail is not in the claims. However, the claims require "an immunostimulating amount of an adjuvant composition." Thus, the claims would do not cover such oligonucleotides that are incapable of stimulating an immune response.

Thus, applicants respectfully assert that undue experimentation would not be required given the working example in the specification showing that an adjuvant in each class work together to provide a superior immune response to *Neisseria meningitidis*. Applicants therefore respectfully request that the Examiner withdraw the enablement rejections.

II. Incorporation by reference

The Examiner has noted that the specification includes incorporations by reference. Applicants thank the Examiner for noting the incorporations by reference. In the event that the referenced subject matter is demonstrated to be essential, Applicants will incorporate the subject matter as appropriate.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002102200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 22, 2010

Respectfully submitted,

By _____

Otis Littlefield
Registration No.: 48,751
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6846
Facsimile: (415) 268-7522